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ROGER A. GILCREST
250 WEST STREET
COLUMBUS, OH 43216-7513

EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,845	HARRIS ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *17-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's amendments, filed 8 January 2007 are acknowledged and entered. Claims 1-34 are pending. Claims 17-34 are withdrawn as being drawn to non-elected inventions. Claims 1-16 are under examination.

Specification - Objections

2. The objection regarding the use of the trademarks is withdrawn in light of Applicant's amendments to the specification.

3. The objection to the disclosure because of the following informalities regarding the blank spaces on page 1 of the disclosure is withdrawn.

4. The objection to the disclosure regarding an obscure square symbol on page 22, last line, is maintained for the reasons of record. Appropriate correction is required.

Benefit

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). It is noted that Applicant's claim for benefit to the earlier filed provisional application under the same title and with the same inventors is in accordance with Applicant's amendment to add the provisional application number and correct the date of filing of the provisional in the first paragraph of the specification. Applicant filed provisional application 60/550,050 on 3 March 2004. No provisional applications were found that were filed by Applicant on 4 March 2004. As such, benefit is granted to provisional application number 60/550,050, filed 3 March 2004.

Provisional Obviousness-Type Double Patenting Rejection

6. The provisional rejection of claims 1-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of copending Application No. 10/842,715, is maintained. The requirement for a terminal disclaimer will be held in abeyance until Applicant is notified of patentable subject matter.

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being indefinite because the claims recite administration for "an effective time" is withdrawn.

9. The rejection of claims 1, 4, 6, 8, 11, and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for referring to "a level" is withdrawn.

10. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn.

11. The rejection of claim 11 for lack of antecedent basis regarding the limitation "said at least one adjuvant" in line 2, is maintained for the reasons of record and the reasons set forth herein. There is insufficient antecedent basis for this limitation in the claim. Claim 11 is dependent from claim 8. However, claim 8 does not encompass the limitation of having "at least one adjuvant."

12. Claim 10 is also rejected as lacking antecedent basis for "said adjuvant." Claim 10 is dependent on claim 8. Claim 8 does not recite an adjuvant. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The rejection of claims 1-16 d under 35 U.S.C. 102(a) as being anticipated by Lernmark et al., Abstract 32-LB, Presented at the ADA meeting, June 2003 (www.diamyd.com/docs/PressDocs.aspx?PageID=11&sm=bc), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the Lernmark et al., reference is Applicant's own work and thus is not prior art under 102(a). Applicant's argument has been fully considered, but it is not persuasive.

The Lernmark et al., reference recites an inventive entity that is different from the three inventors of the instant application. There are 17 co-inventors listed on the Lernmark et al., reference. The term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use. Any other interpretation of 35 U.S.C. 102(a) "would negate the one year [grace] period afforded under § 102(b)." In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

15. The rejection of claims 1-13 and 15 under 35 U.S.C. 102(b) as being clearly anticipated by Kaufman et al., US Patent 6,022,697 (8 February 2000, priority to 29 November 1996), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the reference does not teach or suggest an actual increase in insulin production. Applicant argues that the '697 patent merely speculates that administration of GAD65-antigen could slow down the autoimmune destruction of beta cells in pre-diabetes individuals. Applicant's arguments have been fully considered, but they are not persuasive.

The instant claims do not recite a requirement for an overall increase in insulin production relative to normal insulin production. Instead, the claims recite a method of treating diabetes by administering GAD65 protein and at least one adjuvant to "stimulate the production of insulin...to a level above that existing prior to said administration." As cited in the office action of 7 July 2006, residual islet cell function following GAD65 administration is taught at column 15, lines 27. The '697 patent teaches that a shift from a Th1 response to a Th2 response specific for pancreatic β-cell associated antigen [i.e. GAD65] results in protection against the pancreatic β-cell destruction that is associated with insulin-dependent diabetes mellitus (IDDM)-associated autoimmunity. As such, the correlation between a shift from a Th1 to a Th2 response and protection against the autoimmune-induced destruction of pancreatic β-cells can be exploited for therapeutic purposes (column 5, lines 39-48). The '697 patent also teaches that the severity of an IDDM associated immune response is reduced by administration of a GAD65 protein

and results in a lessening of the detrimental effect or severity of the autoimmune response in the subject receiving therapy (column 9, lines 38-55). Example 5 of the '697 patent teaches that 80% of the mice treated with GAD65 in one particular experiment showed no signs of hyperglycemia compared to control mice that developed IDDM who were not treated with GAD65 (column 14, lines 51-60). The '697 patent specifically teaches that GAD65 administration significantly reduces long term IDDM incidence. Example 6 of the '697 patent teaches that the GAD65-treated mice had residual islet cell function, which allowed them to survive in a chromic hyperglycemic state up to 20 weeks post transplantation of newborn islets when insulin injections were discontinued (column 15, lines 5-29; and Figure 5). Thus, the '697 patent teaches production of insulin in mice treated with GAD65, who retained islet cell function, at a level above that existing prior to the administration. Overall insulin in production in any case would be entirely dependent on the number of surviving insulin-producing islet cells. It is noted that Applicant recognizes this distinction by stating in the response (on page 14 of the Remarks filed 8 January 2007, third paragraph, last sentence) that treatment of LADA (latent autoimmune diabetes in adults) is one way to permit insulin production to increase post-administration, as compared to pre-administration levels; because some beta-islet cell function is retained.

16. The rejection of claims 1-13 and 15 under 35 U.S.C. 102(b) as being clearly anticipated by Diamyd Medical, Press release, Quarterly Report II – 99/00, Stockholm, 3 May 2000 (www.diamyd.com/docs/PressClip.axpx?PageID=10&LangID=2&ClipID-135&sm=b_b), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the reference does not teach or suggest an actual increase in insulin production. Applicant's arguments have been fully considered, but they are not persuasive.

The instant claims do not recite a requirement for an overall increase in insulin production relative to normal insulin production. Instead, the claims recite a method of treating diabetes by administering GAD65 protein and at least one adjuvant to "stimulate the production of insulin...to a level above that existing prior to said administration." The Diamyd Medical press release of 3 May 2000, specifically recites that the "vaccination" against autoimmune illnesses like insulin-dependent diabetes is different from other kinds of vaccination because the immune system is taught to tolerate (not attack) certain self-structures that would otherwise be attacked and destroyed. Such structures include beta cells [the insulin producing cells] in type 1 diabetes (page 1, third paragraph). A composition designed to tolerize the host's immune system against destruction of beta-islet cells, would result an inherent increase

in insulin levels over pre-administration levels, if the beta-cells were under autoimmune attack and were being destroyed.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference does not show a specific recognition of the claim result, it is implied, and its discovery by appellants is tantamount only to finding a property in the old composition." In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966) (emphasis in original).

17. The rejection of claims 1-2, 4-9, 11-16 under 35 U.S.C. 102(b) as being clearly anticipated by Tobin et al., US Patent 5,846,740 (8 December 1998, priority to 21 September 1990), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the reference does not teach or suggest an actual increase in insulin production. Applicant's arguments have been fully considered, but they are not persuasive.

The instant claims do not recite a requirement for an overall increase in insulin production relative to normal insulin production. Instead, the claims recite a method of treating diabetes by administering GAD65 protein and at least one adjuvant to "stimulate the production of insulin...to a level above that existing prior to said administration." The '740 patent teaches that IDDM results from the autoimmune destruction of the insulin producing beta-islet cells of the pancreas. More specifically, the preonset stage is characterized by "insulitis" in which lymphocytes infiltrate the pancreatic islets and selectively destroy the beta-cells. The typical IDDM presentation of hyerglycemia appears only after at least 80% of the insulin-producing beta-cells are lost. The remaining beta-cells are destroyed during the next few years (column 1, lines 26-35). The '740 patent teaches that administration of a GAD protein can ameliorate the autoimmune response against beta-cells by tolerizing the host (column 11, lines 30-38). Induction of tolerance with GAD is taught at column 28, Example 6. In examining the effects of GAD tolerization on diabetes incidence, all of the GAD treated mice had normal glucose levels while 70% of the control mice receiving control antigens developed hyperglycemia (column 29, lines 40-44). A composition designed to tolerize the host's immune system against destruction of beta-islet cells, would result an inherent increase in insulin levels over pre-administration levels, if the beta-cells were under autoimmune attack and were being destroyed.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference does not show a specific recognition of the claim result, it is implied, and its discovery by appellants is tantamount only to finding a property in the old composition." In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966) (emphasis in original).

18. The rejection of claims 1-2, 4-9, 11-13, and 15 under 35 U.S.C. 102(b) as being clearly anticipated by Baekkeskov et al., US Patent 5,998,584 (7 December 1999, priority to 17 October 1997), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the reference does not teach or suggest an actual increase in insulin production. Applicant's arguments have been fully considered, but they are not persuasive. The instant claims do not recite a requirement for an overall increase in insulin production relative to normal insulin production. Instead, the claims recite a method of treating diabetes by administering GAD65 protein and at least one adjuvant to "stimulate the production of insulin...to a level above that existing prior to said administration." The '584 patent teaches a method of inducing of immunotolerance to a GAD65 autoantigen after administration of a composition comprising GAD65 (column 54, lines 56- 62). Compositions comprising GAD65 incorporated into pharmaceutical compositions are taught as being useful to attenuate, inhibit or prevent the destruction of pancreatic β-cells associated with the onset of insulin-dependent diabetes (column 18, lines 64-67 to column 19, line 1). A composition designed to tolerize the host's immune system against destruction of beta-islet cells, would result an inherent increase in insulin levels over pre-administration levels, if the beta-cells were under autoimmune attack and were being destroyed.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference does not show a specific recognition of the claim result, it is implied, and its discovery by appellants is tantamount only to

finding a property in the old composition." In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966) (emphasis in original).

19. The rejection of claims 1-2, 4-9, and 11-16 under 35 U.S.C. 102(b) as being anticipated by Harrison et al., WO 96/26218 (international publication date 29 August 1996), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the reference does not teach or suggest an actual increase in insulin production. Applicant's arguments have been fully considered, but they are not persuasive. The instant claims do not recite a requirement for an overall increase in insulin production relative to normal insulin production. Instead, the claims recite a method of treating diabetes by administering GAD65 protein and at least one adjuvant to "stimulate the production of insulin...to a level above that existing prior to said administration." WO 96/26218 teaches a method of therapeutic treatment of diabetes by inducing immunological tolerance to eliminate or diminish reactivity of autoreactive T-cells or antibodies to IDDM autoantigens using peptides or peptide derivatives of human recombinant GAD65 (page 6, lines 28-32 to page 7, line 2; page 1, line 25; Figure 1. See also, Examples 1 and 2 on p. 7, lines 23-32 to p. 8, line 11). A composition designed to tolerize the host's immune system against destruction of beta-islet cells, would result an inherent increase in insulin levels over pre-administration levels, if the beta-cells were under autoimmune attack and were being destroyed.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). While the reference does not show a specific recognition of the claim result, it is implied, and its discovery by appellants is tantamount only to finding a property in the old composition." In re Tomlinson 363 F.2d at 934, 150 USPQ 623, at 628 (CCPA 1966) (emphasis in original).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Harrison et al., WO 96/26218 (international publication date 29 August 1996) in view of Kaufman et al., US Patent 6,022,697 (8 February 2000, priority to 29 November 1996), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that one cannot extrapolate theoretical contemplations or animal studies or *in vitro* studies to render obvious the efficacy of GAD65-alum in humans because antigen-specific therapy is unpredictable. Applicant's arguments have been fully considered, but they are not persuasive.

Although Applicant argues that animal models are ineffective for comparing a method of treatment of diabetes in mammals and humans, Applicant has failed to provide any data, affidavits, or other evidentiary documentation to support the conclusion that what works well in animal models, will not also work well in humans. Applicant's own prior art work (cited above as Diamyd Medical, Press release, Quarterly Report II – 99/00, Stockholm, 3 May 2000 (www.diamyd.com/docs/PressClip.axpx?PageID=10&LangID=2&ClipID-135&sm=b_b) teaches numerous animal model studies showing the effectiveness of immunization with GAD65 and an adjuvant in animal models of IDDM. Additionally the '740 patent (also recited supra) teaches that, for example, murine and human GAD65 are 95% identical at the amino acid level (555/585) and are 98% conserved

with most of the differences localized near their N-termini (column 32, lines 43-45). Adjuvants comprising alum are well known in the art to be effective in humans as well as animal models.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of WO 96/26218 with the well-known adjuvant, aluminum hydroxide, to effect a method for suppressing or reducing the immune response of a human by administering an immunosuppressive dose of recombinant GAD65 protein in an adjuvant of aluminum hydroxide. The person of ordinary skill in the art would have been motivated to make the modification to select aluminum hydroxide because WO 96/26218 teaches that a pharmaceutical composition of human GAD65 in any adjuvant is acceptable and would produce an immunosuppressive effect against autoreactive T-cells in a dose range of from 0.1μg to 10mg per dose of peptide and preferably 1.0μg to 1 mg per dose of peptide. One of ordinary skill reasonably would have expected success because aluminum hydroxide has been used as an adjuvant since 1934 (see, for exemplary purposes only, Fiejka et al., Rocz Ranstw Zakl Hig. 1993; 44(1):73-80, Abstract Only; HogenEsch H., Vaccine 2002 may 31; 20 Suppl 3:S34-9, Abstract Only; Hem et al., Pharm Biotechnol 1995; 6:249-76, Abstract Only; Redhead et al., Pharmacol Toxicol. 1992 Apr; 70(4):278-80, Abstract Only). Additionally, Kaufman et al., successfully teach administration of recombinant human GAD65 in an adjuvant of aluminum hydroxide.

Conclusion

NO CLAIM IS ALLOWED.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW

AU 1647

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

AU 1647 3/29/07